IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
This document applies to: *Schleck v. Auxilium Pharm. Inc., et al.,* Case No. 1:15-cv-9712	

PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO MOTION OF DEFENDANTS AUXILIUM PHARMACEUTICALS, LLC AND GLAXOSMITHKLINE LLC FOR SUMMARY JUDGMENT

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March 2, 2018

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INTRODUCTION

Defendant Auxilium Pharmaceuticals, LLC (f/k/a Auxilium Pharmaceuticals, Inc., referred to herein as "Auxilium") and GlaxoSmithKline LLC seek summary judgment on the claims brought by Plaintiff Michael Schleck with respect to Auxilium's testosterone replacement therapy ("TRT") product Testim.[1] The motion should be denied because disputed issues of fact preclude summary judgment for Auxilium.

Plaintiff asserts five claims under Florida law: (1) strict liability (design defect); (2) strict liability (failure to warn); (3) negligence; (4) negligent misrepresentation; and (5) fraud.[2] Master Short Form Compl. ¶ 17 (Dkt. No. 1). He seeks both compensatory and punitive damages.

Auxilium argues that all claims fail because Plaintiff cannot offer expert testimony to establish specific causation. This is so, Auxilium concedes, only if the Court grants Auxilium's separate motion to exclude the causation testimony of Plaintiff's expert, Dr. Hossein Ardehali. However, for the reasons set forth in Plaintiff's opposition to the motion to exclude expert testimony, Dr. Ardehali's testimony is reliable and admissible and should not be excluded. Auxilium also argues that all claims are preempted under federal law. As this Court held in CMO No. 76, this argument fails. Auxilium also argues that if the Court grants summary judgment on all of Plaintiff's claims, Plaintiff may not recover punitive damages. The Court should deny Auxilium's motion for summary judgment on Plaintiff's substantive claims and, accordingly, deny summary judgment with respect to Plaintiff's demand for punitive damages.

While Auxilium does not make any claim-specific arguments with respect to his negligence cause of action, Auxilium does makes claim-specific arguments with respect to Mr. Schleck's claims of strict liability (design defect), strict liability (failure to warn), negligent

[1] Plaintiff does not object to the dismissal of GlaxoSmithKline, LLC.

[2] Plaintiff does not object to the dismissal of the breach of implied warranty of merchantability, breach of express warranty, redhibition, negligence per se – violation of 21 U.S.C. §§ 331(a) and 352, and unjust enrichment claims. Auxilium's arguments in sections 5 through 8 are therefore moot.

misrepresentation, and fraud. This portion of Auxilium's motion should also be denied. Plaintiff's failure to warn claims are not barred by the learned intermediary doctrine based on the evidence that Plaintiff's prescribing physician, Darrell Pugh, M.D., would never have prescribed and Mr. Schleck would not have agreed to use Testim had they been adequately warned about Testim's risk of myocardial infarction or lack of efficacy for treating symptoms of aging like weight gain and fatigue. Auxilium is not entitled to summary judgment on Plaintiff's design defect claim because, as this Court has previously held, the evidence regarding Auxilium's marketing of Testim and its warning (or lack thereof) regarding the drug's risks would allow a jury to find Testim to be dangerous to an extent beyond that which an ordinary consumer would expect. Thus, there is sufficient evidence in the record to support a strict products liability design defect claim against Auxilium under Florida law.

A disputed issue of fact precludes summary judgment for Auxilium on the claims of negligent misrepresentation and fraud as there is ample evidence that Dr. Pugh relied on information provided by Auxilium. Dr. Pugh's frequent contact with Testim sales representatives is sufficient evidence for a reasonable jury to infer that Dr. Pugh relied on Auxilium's representations to form his belief that "Low T" was a condition in need of treatment, that Testim was safe and effective for the treatment of age-related hypogonadism, and that Dr. Pugh prescribed Testim on the basis of that belief. For this reason, summary judgment with respect to the negligent misrepresentation and fraud claims is not appropriate.

LEGAL STANDARD

This Court has set forth the legal standard to be applied on a motion for summary judgment in several of its rulings, including its recent decision regarding Auxilium's previous motions for summary judgment. *See* CMO 76, Master Dkt. No. 2210 (October 23, 2017) at 12.

ARGUMENT

I. PLAINTIFF WILL PROVE CAUSATION THROUGH THE EXPERT OPINION OF HOSSEIN ARDEHALI, M.D.

Auxilium argues that Plaintiff has failed to offer any expert testimony on the issue of causation that satisfies the requirements for admissibility under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Plaintiff incorporates by reference Plaintiff's contemporaneously filed Memorandum of Law in Opposition to Motion of Defendant Auxilium to Exclude Expert Testimony, and accordingly, Auxilium's argument should be rejected because Dr. Ardehali's opinions are admissible as grounded in reliable and well-accepted methodologies that were properly performed. Additionally, Auxilium's misunderstanding of the substantial contributing factor test does not undermine the admissibility of Dr. Ardehali's opinion.

For the reasons set forth in the PSC's briefing in opposition to the AbbVie Defendants' motion to exclude Dr. Ardehali's general causation opinion, *see* Master Docket Case No. 1:14-cv-1748, Dkt. No. 1812, and for the reasons set forth by the Court in CMO 46, Dr. Ardehali's general causation opinions should not be excluded. Moreover, Dr. Ardehali performed a reliable differential etiology, an accepted method for establishing specific causation. *Myers v. Illinois Cent. R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010). Dr. Hossein Ardehali offers the case-specific opinion that the "administration of testosterone therapy was a substantial factor in Mr. Schleck's heart attack on January 12, 2014." Ardehali Schleck Report (attached hereto as Exhibit 1) at 12. He explained that "[b]ecause of the use of Testim testosterone product, Mr. Schleck experienced rapid progression of the atherosclerotic plaque formation in his RCA, which caused his MI and myocardial damage" and that the "Testim therapy was a substantial factor in causing this plaque formation because of its effects on reactive oxygen species production and systemic chronic inflammatory disease." *Id.* At his deposition, Dr. Ardehali explained his consideration of each of Mr. Schleck's other risk factors as well as his conclusion that these other factors were not sufficient

to explain the type and timing of Mr. Schleck's heart attack. *See* Ardehali Tr. (attached hereto as Exhibit 2) at 32:11-14; 33:1-21; 42:5-14; 60:3-9. His opinions concerning Mr. Schleck's heart attack show careful consideration of the type of heart attack Plaintiff suffered, Plaintiff's specific medical records relating to the location and extent of his coronary blockages along with an analysis of Plaintiff's specific risk factors and their interaction with his use of testosterone in the process that led to his heart attack. Dr. Ardehali properly performed the differential etiology, carefully explaining why the alternative risk factors were insufficient to cause Mr. Schleck's heart attack and how the biological processes that TRT products initiate interacted with the risk factors Mr. Schleck had and caused his heart attack.

Auxilium's summary judgment motion presents neither the evidence nor the law necessary to meet its burden and its request for summary judgment on the issue of causation should be denied.

II. PLAINTIFF'S CLAIMS ARE NOT PREEMPTED

Auxilium asserts that all of Mr. Schleck's claims are preempted by federal law "in light of the FDA's rejection of a cardiac warning after Plaintiff used Testim," incorporating by reference its argument in the motion for summary judgment based on preemption in the *Holtsclaw* case. Plaintiff requests the Court again reject this argument for the same reasons it was rejected in *Holtsclaw*. *See, e.g.*, CMO 76 at 25 (namely, "[b]ecause Auxilium has not presented clear evidence that the FDA would have rejected its attempts to add a warning about cardiovascular risk to the Testim label, there is no conflict between federal law and [Plaintiff's] failure-to-warn claim.").

III. BECAUSE PLAINTIFF CAN ESTABLISH LIABILITY ON HIS SUBSTANTIVE CLAIMS, HE MAY ALSO RECOVER PUNITIVE DAMAGES

Auxilium asserts that Mr. Schleck cannot recover punitive damages because he cannot establish liability on any of his substantive claims. For the reasons stated herein, the Court should deny Auxilium's motion for summary judgment on Plaintiff's substantive claims and, accordingly,

deny summary judgment with respect to Plaintiff's demand for punitive damages. Plaintiff also notes that the applicable law for his request for punitive damages is Pennsylvania law because the state in which the defendant is domiciled has a stronger policy interest in whether punitive damages are available. *See* CMO 47 at 50–52 (applying "most significant contacts" test); Defs.' Statement of Facts, ¶ 2 (identifying Auxilium's principal place of business as Chesterbrook, Pennsylvania).

IV. DISPUTED ISSUES OF FACT PRECLUDE SUMMARY JUDGMENT FOR AUXILIUM ON PLAINTIFF'S STRICT LIABILITY, NEGLIGENT MISREPRESENTATION, AND FRAUD CLAIMS

1. The Learned Intermediary Doctrine Does Not Bar Plaintiff's Failure to Warn Claims Because There Is Ample Evidence that Dr. Pugh Would Have Altered His Conduct Had He Been Properly Warned about Testim's Lack of Efficacy and Cardiovascular Risks

Auxilium argues that Plaintiff cannot establish proximate causation because he "cannot establish that any allegedly inadequate warning was the proximate cause of Dr. Pugh's decision to prescribe Testim for Plaintiff." Defs.' Br. at 9. In the context of a claim for failure to provide an adequate warning of a product's dangers, "proximate causation" under Florida law refers to a showing that an adequate warning would have *altered the treatment* of the prescribing physician. *Chiles v. Novartis Pharm. Corp.*, No. 3:06-CV-96-J-25 JBT, 2013 WL 5769903, at *7 (M.D. Fla. Feb. 7, 2013) ("Because Dr. Moreb would have let his patient decide and Plaintiff stated he would not have taken Zometa® if he knew of the risk, this combined testimony is sufficient to demonstrate adequate warnings would have altered Plaintiff's Zometa® treatment.").

For claims regarding prescription drugs, the proximate causation analysis is viewed through the prism of the "learned intermediary doctrine." Under that doctrine, a manufacturer of a prescription drug need not provide its warning directly to the patient; it must instead provide the warning to the prescribing physician who acts as a "learned intermediary" between the manufacturer and the patient. Where the patient plays an active role in his medical treatment and the doctor communicates risks to the patient to allow him to make an informed decision about his

care, the Court must assess proximate causation with respect to the effect of the inadequate warning on the doctor's overall prescribing behavior – in particular the doctor's risk-benefit discussion and the patient's ultimate decision to choose the medication. *In re NuvaRing Products Liab. Litig.*, No. 4:08-CV-00558-RWS, 2013 WL 3716389, at *10 (E.D. Mo. July 12, 2013).

Numerous recent Florida pharmaceutical cases have held that summary judgment is improper where an adequate warning would have changed the prescribing doctor's risk-benefit discussion and the patient would not have used the drug had they know of the risk. *See e.g. Guenther v. Novartis Pharm. Corp.*, 990 F. Supp. 2d 1299, 1304-05 (M.D. Fla. 2014), *appeal dismissed* (Feb. 26, 2015) (denying summary judgment where plaintiff "testified that if she had been warned by her oncologists about the risk of ONJ, she would have refused to take Zometa, and that she did stop taking the drug once she was told of that risk"); *Dopson-Troutt v. Novartis Pharm. Corp*., No. 8:06-CV-1708-T-24, 2013 WL 1344732, at *4 (M.D. Fla. Apr. 2, 2013) (denying summary judgment where plaintiff "testified that she would not have continued taking the drugs if she had been adequately warned about their risks"); *Munroe v. Barr Labs., Inc*., 670 F. Supp. 2d 1299, 1305 (N.D. Fla. 2009) (holding that Florida's learned intermediary doctrine did not entitle the drug manufacturer to summary judgment where a juror could infer that a better warning would have changed the physician's instructions to the patient, and the patient would have heeded the instructions). Thus, even under the learned intermediary doctrine, Auxilium cannot show that it is entitled to summary judgment on the issue of proximate causation because the evidence sufficiently demonstrates that Dr. Pugh would have changed his treatment in prescribing Testim had he known it lacked efficacy and carried significant risk of myocardial infarction.

1. Mr. Schleck's Prescribing Physician Was Not Aware of Testim's Heart Attack Risk and Lack of Efficacy for Age-Related Hypogonadism before Mr. Schleck Suffered His Heart Attack

It is beyond dispute that Testim's product labeling failed to include a warning of myocardial infarction. In fact, Dr. Pugh specifically testified in this regard:

> Q. What I want to ask you is, first of all, your risk-benefit discussion with Mr. Schleck at that January 2013 would have been consistent with what was known to you from the product labeling like this; right?
>
> A. One of the reasons, yes.
>
> Q. Okay. And the product labeling here, the warnings and precautions section, do you see any reference to the potential for specifically a heart attack?
>
> A. Not specific heart attack. Only thing I'd reference would be 6.
>
> Q. Would be what?
>
> A. Number 6.
>
> Q. The edema?
>
> A. Yes.
>
> Q. Okay. Which edema is what, now?
>
> A. Fluid retention.
>
> Q. Okay. Fluid retention. Alright. It's not a heart attack; correct?
>
> A. No.
>
> …
>
> Q. Can you testify here today that in January 2013 or any time while he was on Testim that you specifically warned him if he took the product, he was at risk for a heart attack, that those words would have come out of your mouth?
>
> A. I don't know about the specific words.
>
> Q. Okay.
>
> A. I couldn't tell you.

Pugh Tr. (attached hereto as Exhibit 3) at 186:3-23; 193:3-11. He also testified that his risk-benefit discussion was based on the label and information available at the time. *Id*. at 191:15-18. ("[T]hings change over time. So I can't give you information today that won't be different tomorrow. I can give you the best facts that I know.").

Dr. Pugh also testified that he would not have prescribed Testim to Mr. Schleck if it did not confer a benefit. *See id.* at 141:23-142:2. Importantly, Dr. Pugh also admitted that he prescribed Testim to Mr. Schleck in part because of his age.

> Q. Okay. And in considering the root cause of Mr. Schleck's low testosterone in the 2013, 2014 time period, would you agree that his low testosterone levels were most likely caused by his weight, his high cholesterol, and his age?

[Objection]

A. Yes.

Id. at 140:9-15. He also testified that he had not seen documents demonstrating the FDA's concerns regarding age-related hypogonadism while also acknowledging that he viewed the FDA as authoritative in this field. *Id*. at 150:18-151:6; 155:1-8; *see also id.* at 151:3-6; 153:7-12 (testifying that he had no memory of discussing the FDA's statements regarding TRT's lack of efficacy with Auxilium sales representatives).

In sum, Dr. Pugh lacked critical information regarding Testim's benefits and risk of myocardial infarction, and specifically, did not have the information Plaintiff contends Auxilium was obligated to provide. In other words, Dr. Pugh was unaware of Testim's lack of efficacy for age-related hypogonadism and the risk of myocardial infarction with Testim in the 2012 to 2014 time frame.

2. The Jury Could Find that Dr. Pugh and Mr. Schleck Would Both Have Altered Their Conduct if They Had Been Warned about Testim's Lack of Efficacy and Heart Attack Risk

During Mr. Schleck's course of Testim usage, Dr. Pugh was unaware of the risk of myocardial infarction associated with Testim. *Id.* at 186:3-23; 193:3-11. Equally as important, Dr. Pugh stated that if he knew that Testim carried the risk of myocardial infarction he would have either not prescribed Testim to Mr. Schleck or, at a minimum, would have shared that information with him during their risk-benefit discussion. *Id.* at 158:3-13 ("It's a benefits-risk ratio and what the patient wants. You know, obviously, if I knew that it caused heart attacks specifically and it was a proven fact, then, of course, I would want to avoid that … But, again, it comes down to a conversation with the patient, and, ultimately, the patient decides if he's willing to accept the risk or not."). Dr. Pugh also testified that had he known there was insufficient evidence to establish a benefit with Testim and potential cardiovascular concerns in January 2013 he would have discussed with Mr. Schleck less risky treatment options than the use of testosterone. *Id*. at 158:21-

160:4. Furthermore, Dr. Pugh testified that he specifically did *not* warn Mr. Schleck of the risk of heart attacks with Testim. *Id*. at 160:5-23 (explaining that he would have discussed coronary artery disease with Mr. Schleck but specifically *not* the risk of heart attack). It should also be noted that Mr. Schleck testified that he depended on Dr. Pugh to advise him of Testim's risks and benefits and that he stopped using Testim as soon as he was informed that Testim could cause a heart attack. Schleck Tr. (attached hereto as Exhibit 4) 164:9-12; 157:17-22. Thus, the jury could find that Mr. Schleck would have not used Testim had Dr. Pugh warned him either of Testim's heart attack risk or that Testim was not efficacious in treating the symptoms of aging like fatigue and weight gain.

In sum, based on Plaintiff's evidence a jury could find that, confronted with an adequate warning about the risk associated with Testim or the lack of efficacy for fatigue and weight gain, Mr. Pugh would never have been prescribed the drug. The testimony of Plaintiff's prescribing physician, Dr. Pugh, showed that the prescribing decision he made with respect to Mr. Schleck was made collaboratively with Mr. Schleck, and that the decision would have been affected by an adequate warning about heart attack risks or the lack of efficacy with treating weight gain and fatigue. Taken together, the testimony of Dr. Pugh and Mr. Schleck is sufficient to create a triable issue of fact as to the difference an adequate warning would have made.

2. Auxilium is Not Entitled to Judgment with Respect to Plaintiff's Design Defect Claim Because There is Sufficient Evidence in the Record that Testim is Unreasonably Dangerous

Auxilium has also moved for summary judgment on Mr. Schleck's claim for strict liability design defect. Auxilium's sole argument is that "Plaintiff's design defect claims should be dismissed because he has not retained any expert who will opine on Testim's design, rather than Auxilium's alleged off-label marketing." Defs.' Br. at 11. Auxilium is wrong.

Testim is dangerous because it is marketed for treatment of the wrong conditions and is not accompanied by adequate warnings of the drug's risks. Under Florida law, a manufacturer of a product may be held liable for an injury caused by the product if that product was "unreasonable

dangerous." *See Aubin v. Union Carbide Corp.*, 177 So.3d 489, 503 (Fla. 2015). A product is unreasonable dangerous in design if "it failed to perform as safely as an ordinary consumer would expect when used as intended." *Id., citing* Restatement (Second) of Torts § 402A (1965). As this Court has previously held, the evidence regarding Auxilium's marketing of Testim and its warning (or lack thereof) regarding the drug's risks would allow a jury to find Testim to be dangerous to an extent beyond that which an ordinary consumer would expect. Moreover, and contrary to Auxilium's contention, Plaintiff does have expert testimony supporting his assertion that Testim's label lacked adequate safety and efficacy for age-related hypogonadism and failed to include a heart attack warning. *See, e.g.,* Rpt. of Peggy Pence (attached hereto as Exhibit 6). Thus, there is sufficient evidence in the record to support a strict products liability design defect claim against Auxilium under Florida law. *See* CMO No. 76 at 27-29 (holding same under Tennessee law).

3. Dr. Pugh Relied on Information Provided by Auxilium Such that Summary Judgment on Fraud and Negligent Misrepresentation Must be Denied

Auxilium argues that the Court should grant summary judgment on Mr. Schleck's negligent misrepresentation and fraud claims because he has failed to satisfy his burden to show that Dr. Pugh received and relied upon a misrepresentation made by Auxilium. It is true that Mr. Schleck has not identified any direct evidence that Dr. Pugh relied upon any *particular* misrepresentation from Auxilium when deciding to prescribe Testim to Mr. Schleck. However in viewing the evidence in the light most favorable to Mr. Schleck – evidence that includes Dr. Pugh's frequent contacts with Testim sales representatives and Dr. Pugh's admission that he relies upon Auxilium for accurate information about Testim's risks and benefits – a reasonable jury could infer that Dr. Pugh relied on Auxilium's representations to form his belief that Testim was safe and effective for the treatment of age-related hypogonadism and that Dr. Pugh prescribed Testim on the basis of that belief.

As this Court noted before, "[a] plaintiff need not show that his (or … his physician's) reliance was the sole or even the predominant influence; rather, it is enough that the representation has played a substantial part, and so has been a substantial factor, in influencing his decision." CMO 48, Dkt. No. 1897 (May 8, 2017) at 18 (internal citation omitted); *see also Whitney v. R.J. Reynolds Tobacco Co.*, 157 So. 3d 309 (Fla. Dist. Ct. App. 2014), *reh'g denied* (Feb. 26, 2015) ("[A] defendant's conduct need not be the only cause of a plaintiff's injuries, or even fifty-one percent of the cause; rather, the plaintiff must present evidence that the defendant's conduct was, more likely than not, a "substantial factor" in causing the injury."). "[E]xcept in the rare case where the undisputed facts leave no room for a reasonable difference of opinion, the question of whether a plaintiff's reliance is justified is a question of fact." *Id.* (citation omitted). The evidence here is sufficient to support a reasonable finding by a jury that Dr. Pugh relied on Auxilium's alleged misrepresentations regarding the safety and efficacy of testosterone replacement therapy in general, and Testim specifically, in prescribing the drug for Mr. Schleck.

Based on Dr. Pugh's testimony a jury could find that he was exposed to, and believed, off-label marketing claims that Testim was an appropriate treatment for a variety of conditions related to aging in men who never had hypogonadism as defined by the Testim label. As has been previously discussed at great length, there is no evidence that TRT products provide any benefit in men with age-related declines in testosterone and the FDA never approved any TRT products for that use. *See, e.g.*, Plfs.' Auxilium *Daubert* Opp., Master Dkt. No. 2173. Yet Dr. Pugh repeated point-for-point Auxilium's marketing message: he believed that fatigue, weight gain, and lack of libido are the main symptoms of "hypogonadism." *See* Ex. 3 at 36:2-3. He believed that for men with these symptoms Testim provides a treatment option to decrease obesity and improve lipid profile, lean muscle mass, and insulin sensitivity. *Id.* at 33:5-34:14. Given the lack of scientific support for these beliefs – and statements from the FDA emphasizing the lack of scientific support

for these claims – a jury could conclude that Auxilium was, at least in part, the source of these beliefs. A true story may emanate from many places, but a particular falsehood is more easily traced back to its source. Dr. Pugh could have learned the truth about testosterone from many sources unconnected to Auxilium, but the "Low T" story bears the signature of Auxilium and other TRT product manufacturers and marketers.

Dr. Pugh testified that he prescribed Testim to Mr. Schleck for his fatigue and weight gain. *Id.* at 116:14-117:7. Importantly, Mr. Schleck was not diagnosed with primary hypogonadism or any other condition indicated in the label. Dr. Pugh testified:

> Q. Now, would I understand correctly that your diagnosis of hypogonadism for Mr. Schleck was based on the testosterone levels that you took and the symptoms he presented with?
>
> A. Yes.
>
> Q. Okay. And so would I also be correct in stating that during the time that Mr. Schleck was taking Testim, that you did not diagnose him with any disease of the pituitary gland?
>
> A. I did not.
>
> Q. Okay. And would I also be correct that while the time that Mr. Schleck was taking Testim, you did not diagnose him with any disease of the testicle?
>
> A. Correct.
>
> Q. And, as a general proposition, do you understand that testosterone levels decline naturally with aging?
>
> A. Yes.
>
> Q. Okay. And in considering the root cause of Mr. Schleck's low testosterone in the 2013, 2014 time period, would you agree that his low testosterone levels were most likely caused by his weight, his high cholesterol, and his age?
>
> [Objection]
>
> B. Yes.

Id. at 139:14-140:15.

The misrepresentations at issue include: (1) that "low testosterone" was a disease, (2) that age-related "low T" should be treated even without discovering the underlying condition; (3) that based on a testosterone measurement alone and vague symptoms such as loss of energy or weight

gain Testim could be prescribed without a full endocrinology workup and without a diagnosis of the cause of the lab test; and (4) that testosterone could be safely prescribed and was appropriate for treating low energy and weight gain. Dr. Pugh prescribed Testim based on a vague complaint of low energy and weight gain.

Moreover, a jury could conclude that Auxilium was the source of Dr. Pugh's beliefs. Testim sales representatives called Dr. Pugh at least 116 times. *See* Defense Fact Sheet (attached hereto as Exhibit 5) (attaching over 1,200 pages worth of sales representative call notes, items left with Dr. Pugh, IMS data, and financial payment records to Dr. Pugh). These office calls included at least 8 sales presentations about Testim during which Dr. Pugh was provided a snack or meal. *Id.* at 1207-8*; see also* Ex. 3 at 167:6-18 (noting Dr. Pugh's love for Krispy Kreme doughnuts). During these sales calls, Testim sales representatives provided copies of company-approved Testim promotional materials to Dr. Pugh. *See* Ex. 5 at 38-70. Dr. Pugh testified that he was provided with materials by Testim sales representatives. Ex. 3 at 129:13-16.

This evidence is sufficient that a jury could find that the off-label marketing campaigns affected Mr. Schleck's prescriber, even if Dr. Pugh did not admit to relying on marketing or recall any specific marketing information he received. A jury could find that Auxilium's information and promotional materials were sufficient to convince Dr. Pugh that there was a condition called "Low T" associated with loss of energy and weight gain and that patients like Mr. Schleck would benefit from using the drug.

In addition, a jury could find that Auxilium omitted information necessary to make its statements not misleading. Not only did Auxilium misrepresent the benefits of Testim, it also understated and failed to disclose the risks associated with it. Based on Dr. Pugh's testimony a jury could find that Dr. Pugh weighed Testim's risks and benefits for Mr. Schleck based on the information available to him.

Taken together, this evidence is sufficient for a jury to find that Dr. Pugh's prescribing decision was influenced by Auxilium's marketing information and the absence of warnings about the cardiovascular risks of Testim. At the summary judgment stage, Plaintiff is entitled to all reasonable inferences and to view the evidence in the light most favorable to him. *United States v. King-Vassel*, 728 F.3d 707, 717 (7th Cir. 2013); *McGreal v. Ostrov*, 368 F.3d 657, 663 (7th Cir. 2004); *Tolliver v. City of Chicago*, 821 F.3d 237, 239 (7th Cir. 2016). Applying this standard there are material issues of fact that preclude summary judgment based on the question of reliance.

CONCLUSION

For the foregoing reasons, this Court should deny Auxilium's motion for summary judgment.

Dated: March 2, 2018

Respectfully submitted,

/s/ Brandon Bogle

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CERTIFICATE OF SERVICE

I hereby certify that on March 2, 2018, I electronically transmitted the foregoing document to the Clerk of the United States District Court using the CM/ECF system for filing and service to all parties/counsel registered to received copies in this case.

/s/ Brendan A. Smith
Brendan A. Smith